REMARKS

Preliminarily, Applicant would like to direct the Examiners attention to a transcription error that occurred in the Amendment filed on September 7, 2004, in the above-identified patent application. Claim 12, as originally filed, contained the phrase "and recall information" in subsection (d.). A scribner's error occurred when transcribing Claim 12 in the September 7, 2004 Amendment, wherein the phrase "and recall information" was inadvertently left out of subsection (d.). Currently amended Claim 12 contains the phrase as originally filed. As such, reinstatement of the phrase does not constitute new matter. Applicant regrets that the error occurred and apologizes for any inconvenience this may have caused the Examiner.

Turning to substantive matters, on page 2 of the Office Action, the Examiner rejected Claims 1, 3-5, 7-11 and 14-18 under the provisions of 35 U.S.C. 102(b) as being anticipated by United States Patent No. 5,845,255 to Mayaud (hereinafter "the `255 Patent" or "Mayaud").

For the reasons set forth below, the rejection is respectfully traversed.

The claims, as presently amended, are directed to an internet-based universally compiled data repository system with access to a locally compiled database for medical product information and its dissemination upon administration of a medication to an institutionally based patient. The system provides a database (pre and post-prescribing), for dissemination of information and identification of institutionally dispensed medications, combinations of medications, and/or patient-specific prepared medications (including the plethora of extemporaneously compounded medications, e.g. IV admixtures), upon their administration to an institutionally based patient.

Support for the amendment is found generally throughout the specification and specifically at page 6, lines 6-13, page 8, lines 19-23, page 14, lines 13-17, page 15, lines 3-11 and page 20, lines 1-7.

The present system provides for novel access and use of specially defined and designed product descriptions, safety codes, product scan codes, product equivalencies, product recall information, and at least one medication identifier and information

comprising NDC numbers having associated lot/control/batch numbers and expiration dates, GTIN numbers and UPC Codes for institutionally dispensed medication at the actual point of administration to hospital based patients.

As is well settled, anticipation requires "identity of invention." There must be no difference between what is claimed and what is disclosed in the applied reference. Moreover, it is incumbent upon the Examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *See* MPEP §2131. The reference must teach every aspect of the claimed invention either explicitly or impliedly. *See* MPEP § 706.02

In this regard, the rejection fails to identify where in Mayaud each and every element of claims 1, 3-5, 7-11 and 14-18 are shown. In particular, there is no teaching in Mayaud, express or implied of the required user's access to a database having, among other things, specially defined and formatted product descriptions, including NDC numbers; safety codes; and product scan codes. Further, Mayaud fails to disclose accessing the information **upon administration of a medication to an institutionally based patient**.

More particularly, Mayaud is directed to an "electronic prescription pad" where a prescribing physician accesses information on a drug or combination of drugs at the time the drugs are prescribed. Of course, this information does not guarantee that the warnings or recalls after the prescription is written but prior to the administration to the patient will be discovered.

In sharp contrast to Mayaud, the present claimed invention permits the information to be checked **at the time of administration**. This system ensures that critical information is available on a real time basis at the time of administration of a drug or combination of drugs.

Because Mayaud does not include these claimed elements, the rejection should be withdrawn.

On page 7 of the Office Action the Examiner rejected Claims 2, 6 and 12-13 under the provisions of 35 U.S.C. § 103(a) as being unpatentable over Mayaud in view of Portwood et al., United States Patent No. 6,305,377 (hereinafter "Portwood").

For the reasons set forth below, the rejection is respectfully traversed.

In forming this rejection the Examiner acknowledged that Mayaud "does not teach wherein the product scan codes include at least one medication identifier and information comprising at least one of the items selected from the group consisting of: NDC number having associated lot/control/batch numbers and expiration date, GTIN number and UPC Code." (Office Action at paragraph 5.)

To fill the acknowledged gap, the Examiner looked to Portwood as "teach[ing] a system and method for improving compliance of a medical regimen (See abstract), in which he teaches the product scan codes include at least one of the items selected from the group consisting of: NDC number having associated lot/control/batch numbers and expiration date, GTIN number and UPC Code." (Office Action at item 5.)

The Examiner reasoned it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have modified Mayaud to use "**product scan codes**" to include at least one medication identifier and information comprising at least one of the items selected from the group consisting of: NDC number having associated lot/control/batch numbers and expiration dates, GTIN number and UPC Codes.

However, Portwood discloses a system for improved compliance by a patient with a medical regimen including comparing prescribing information **prior to dispensing** and "reminder notifications" to tell a non-institutionally based patient when to take his or her medicine (*see* Abstract; Col. 2, lines 17-56; and Claim 1). Portwood further discloses "a second medical problem relating to medical regimens" as a lack of checking procedures and suggests the use of GPI, NDC and KDC codes to verify a prescriptions compliance with a recommended regimen (see Col. 1, lines 50-65).

A fair reading of both Mayaud and Portwood fails to disclose the present concept of "product scan codes," as currently claimed, with only Mayaud's mere reference to bar code labels for test requirements relating to patient preparations, such as fasting or sample collection. *See* Mayaud at column 52, lines 27-32. Further more, neither of the references teach or even remotely suggest obtaining information at the time of administration to an institutionally based patient.

For a *prima facie* case of obviousness to be established, the teachings from the prior art itself must have suggested the claimed subject matter to one of ordinary skill in the art. The mere fact that the prior art could be modified as proposed by the Examiner is not sufficient to establish a *prima facie* case of obviousness.

In the present case there is not any suggestion or motivation (express or implied) based on Portwood or Mayaud to include, among other things, product scan codes with at least one medication identifier and information comprising at least one of the items selected from the group consisting of NDC, GTIN and UPC Codes to be included in institutionally dispensed medications - for the dissemination of information upon their administration. It is not seen where the disclosure of GPI, NDC or KDC identification codes furnished to a "prescriber" in an effort to overcome a lack of checking procedures **prior to writing a prescription** would provide the requisite motivation to include this information upon administration of an institutionally dispensed medication to an institutionally based patient.

Specifically, Mayaud describes an "electronic prescription creation system for physician use" to access third party formularies **prior to writing a prescription**, and Portwood teaches "improving compliance" by checking the medical regimen **prior to dispensing** and alerting the patient to take the medication. As such, the cited prior art provides no safety check of hospital dispensed medications such as IV admixtures, specialty compounded IV's for chemotherapy, specialty compounded IV's for surgery, and extemporaneously compounded IVs, to name a few, that are prepared sometimes weeks in advance of administration, at the time of administration. The novel feature of the present invention provides all of the safety features discussed herein, immediately prior to the medication's administration, which is neither taught nor suggested by Mayaud or Portwood.

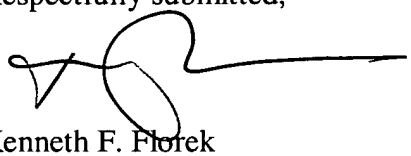
The resulting combination of Portwood's medication identifiers and Mayaud's assisted prescribing system does not result in the claimed invention and does not solve the problem of supporting a medication safety program for institution based patients at the time of administration of a medication.

For these reasons, applicant respectfully submits that the rejection is improper and should be withdrawn.

Finally, the Examiner is invited to call the applicants' undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be full condition for allowance, for any reason, the applicant respectfully requests the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP §707.07(j) or in making constructive suggestions pursuant to MPEP §706.03 so that the application can be placed in allowable condition as soon as possible and without the need for further proceedings.

In light of the foregoing, favorable consideration is respectfully requested and earnestly solicited at this time.

Respectfully submitted,



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